510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k061181

B. Purpose for Submission:
Change in volume required, strip application port, read time, outer casing, and addition of Alternate testing sites.

C. Measurand:
Glucose

D. Type of Test:
Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:
TaiDoc Technology Corporation

F. Proprietary and Established Names:
ACHTUNG TD-4207 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345, Glucose Test System
2. Classification:
   Class II
3. Product code:
   NBW, CGA
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   See Indications for use.
2. Indication(s) for use:
   The ACHTUNG Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.
   The alternative site testing in the ACHTUNG Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.
3. Special conditions for use statement(s):
   For Over-the-Counter use.

The alternative site testing in the ACHTUNG Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

Alternate site samples should ONLY be used in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal)
- Two hours or more after taking insulin
- Two hours or more after exercise

4. Special instrument requirements:
   ACHTUNG TD-4207 Blood Glucose Monitoring System

I. Device Description:

The ACHTUNG TD-4207 Blood Glucose Monitoring System consists of four main products: the blood glucose meter, test strips (including the "check & code" strip), control solutions (2 levels of Taidoc control solution – cleared under k012430), and the lancet device (cleared under k833344). The sponsor recommends that only ACHTUNG test strips and control solutions be used with the ACHTUNG blood glucose meter. The performance of the test strips is verified by the control solutions. The check & code strip verifies the status of the meter. For a more detailed description, see k042005 and k041107.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ACHTUNG TD-4207, Clever Chek TD-4209, Clever Chek TD-4222 Blood Glucose Test System
2. Predicate 510(k) number(s):
   k042005
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Temperature Range	50-104°F, 10-40°C	50-104°F, 10-40°C
Humidity Range	Below 85%	Below 85%
Warranty (meter)	5 years	5 years
Open Use Time (strip)	90 days	90 days
Coding	Code strip	Code strip
Memory Capability	450 measurements	450 measurements
Power	CR2032 3V lithium battery	CR2032 3V lithium battery

Differences		
Item	Device	Predicate
Sample Source	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, forearm, upper arm, calf, and thigh.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip.
Test Strip Blood Application Port	Top	Side
Casing	Rounded	Square
Test Time	7 seconds	10 seconds
Sample Volume	0.7 µL	1.5 µL
Description and Labeling	Alternate site testing (AST) information listed in the user's manual and packaging.	No information listed.

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
CLSI EP9-A: Method Comparison and Bias Estimation Using Patient Samples
ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

See k042005 and k041107 for more information.

L. Test Principle:

Once a whole blood sample is applied to the sample chamber of the test strip, glucose measurement commences. Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, producing gluconolactone. The current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   The sponsor evaluated the precision of the device using replicate measurements of glucose control solutions and anticoagulated venous whole blood. In order to determine that the change in sample volume does not affect precision, the sponsor tested four volume levels (0.5, 0.6, 0.7, and 0.8 µL) of venous whole blood collected from 10 volunteers. The ten samples were pooled together, depleted of glucose, and then separated into three groups. Each group was spiked with a dextrose solution to within the desired concentration range: low 60-92 mg/dL, normal 109-165 mg/dL and high 259-389 mg/dL. Different testing volumes (0.5uL, 0.6uL, 0.7uL and 0.8 uL) of each sample were evaluated for repeatability. Since the volume claimed is 0.7 µL,

only the 0.7 µL data is presented below.

Patient	Low Control Level (60-92 mg/dL)			Mid Control Level (109-165 mg/dL)			High Control Level (259-389 mg/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
1	68	68	72	139	139	144	309	309	300
2	68	68	65	132	132	141	310	310	297
3	70	70	71	130	130	133	314	314	307
4	68	68	71	136	136	137	308	308	300
5	72	72	70	133	133	141	311	311	297
6	72	72	72	133	133	134	312	312	313
7	70	70	74	137	137	131	306	306	305
8	69	69	71	135	135	134	313	313	302
9	65	65	69	134	134	141	310	310	301
10	64	64	74	137	137	145	305	305	305
Total CV (%)	3.98			2.85			1.60		

b. Linearity/assay reportable range:
The linearity of the device was originally demonstrated in k041107. The sponsor verified accuracy of the device over the reportable range (20 – 600 mg/dL) against a standard detection method (see Method Comparison below).

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The controls supplied with this device were previously cleared under k012430. The sponsor has shown traceability of the meter to a laboratory analyzer. The sponsor has described their strip stability testing protocol and acceptance criteria which were found to be acceptable.

d. Detection limit:
The measuring range of the ACHTUNG TD-4207 Blood Glucose Monitoring System is 20 - 600 mg/dL.

e. Analytical specificity:
The specificity of the device was assessed in k041107. Given that the fundamental technology has not changed from k041107, the sponsor claims that elevated blood triglycerides and the following substances do not affect results: acetaminophen, dopa, methyldopa, L-dopa and tolbutamide occurring in expected blood concentrations. Due to the change in read time of the glucose oxidase reaction, the sponsor provided studies of reducing substances along with an altitude study for the new strips. Reducing substances such as uric acid and ascorbic acid occurring in expected blood concentrations (0-3 mg/dL and 5-20 mg/dL respectively) were shown not interfere with glucose measurements. The altitude study also showed that the percentage of mean difference between strips is within the acceptable range (as defined by ISO 15197: within ±20% when glucose concentration **>**75mg/dL)

indicating that the new test strips are equivalent to the predicate strips at the same altitude (up to 10,744 feet).

f. Assay cut-off:
Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:
The sponsor demonstrated that the ACHTUNG TD-4207 Blood Glucose Monitoring System for finger stick is equivalent to a standard method (YSI-2300) and can be used on alternate sites (specifically the capillary blood from finger compared to the palm, forearm, upper arm, calf, and thigh) by having 120 patients for the standard method compared to finger stick and 100 patients for each alternate site test the meter. For the finger stick against the standard method, samples ranged as follows: 10% of samples were 20-50 mg/dL, 35% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 10% of samples were 151-250 mg/dL, 10% of samples were 251-400 mg/dL, and 5% of samples were 401-600 mg/dL. For the AST sites, the samples ranged as follows: 40% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 20% of samples were 151-250 mg/dL, and 10% of samples were 251-400 mg/dL. All patients blood glucose levels were in a steady state for these studies. The studies are summarized below:

	YSI vs. Finger	Finger vs. Palm	Finger vs. Forearm	Finger vs. Upper arm	Finger vs. Calf	Finger vs. Thigh
N	120	100	100	100	100	100
Slope	1.0052	1.0057	0.8716	0.9102	0.9173	0.9842
Intercept	1.7264	1.8744	9.1884	6.2178	5.3413	0.7822
r	0.9948	0.9889	0.9839	0.9822	0.9822	0.9805

Finger versus YSI and each site met the ISO 15197 standard of ninety-five percent (95 %) of the individual glucose results falling within ±15 mg/dL of the results of the comparator method at glucose concentrations for samples <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL. The samples that met the ISO 15197 requirement are summarized in the table below:

Site	Finger	Palm	Forearm	Upper arm	Calf	Thigh
N	120	100	100	100	100	100
Percentage That Met ISO Requirement	100% (120/120)	99% (99/100)	100% (100/100)	98% (98/100)	98% (98/100)	98% (98/100)

The sponsor also has labeling indicating the conditions under which AST can be used and when AST should not be used.

b. Matrix comparison:
See above: *Method comparison with predicate device*

3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable.
   b. Clinical specificity:
   Not Applicable.
   c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:
   Not Applicable.

5. Expected values/Reference range:
   The sponsor included the following Expected Values for normal glucose levels in their strip labeling:

Status	Range (mg/dL)	Range (mmol/L)
Before meals	70-110	3.9-6.1
2 hours after meals	<120	<6.7

   Source: Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual. Philadephia: Lea and Febiger (1989), 138.

N. Instrument Name:

ACHTUNG TD-4207 Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for additional readings.
2. Software:
   FDA reviewed applicant's Hazard Analysis and software development processes for this line of product types in k041107. See k041107 for more information.
3. Specimen Identification:
   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.
4. Specimen Sampling and Handling:
   This device is intended to be used with capillary whole blood from the finger, the palm, the forearm, the upper-arm, the calf, and the thigh only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.
5. Calibration:
   A code strip is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.
6. Quality Control:
   The sponsor is providing a high and low glucose control solution with this device. When a test strip is inserted into the meter, the control mode can be activated. This prevents control results from being stored in the internal memory. An acceptable range for each

control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.